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Jeff Fisher, R.Ph.
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July 29, 1999
The Food and Drug Administration
5630 Fisher's Lane
Rockville, MD. 20852

Dear Sirs:

As one of the owners of Fisher's SPS, Inc., a compounding pharmacy, I was pleased to see the passage of section 127 of the FDA Modernization Act of 1997. We believe that the Congress clearly wanted states to have a mechanism to investigate safety complaints for those compounded products shipped out of state, but the FDA's proposed MOU creates hardships for state boards of pharmacy, the compounding pharmacist, and above all the patient.

Fisher's SPS is a specialized pharmacy located in Pittsburgh, Pennsylvania that offers treatment to patients with specific disease states like HIV or Hepatitis and is also a specialized compounding pharmacy. Fisher's has already developed a regional reputation in connection with its disease state management and compounding services and currently services patients not only in the Pittsburgh area, but also in West Virginia and Ohio. Many of these patients are located more than 50 miles from Fisher's and, therefore, would not meet the 50-mile limit in the proposed MOU. Fisher's is also currently developing a national reputation and anticipates compounding prescriptions upon the receipt of valid prescription orders for customers nationwide. I would like to stress that we are a highly ethical pharmacy and comply with all state and federal laws and licensing requirements for any state we may have patients in.

The MOU as it reads today will prevent us from serving patients who need our specialized services in other states. Please consider eliminating any caps on interstate compounded prescriptions, or establish "safe harbors" that would permit interstate shipment in excess of 5% of prescription orders. These "safe harbors" could be for compounded drugs related to unique disease states like HIV and Hepatitis where it is difficult for patients to find a pharmacy like ours that can meet their needs.

Sincerely,

Donald J. Kerrish RPh

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Phyllis Norris
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Department of Health & Human Services
Rockville, MD 20852-2000

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